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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/380,310	08/31/1999	KOJI UKAI	0425-0736P	2449

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EXAMINER	
HAGHIGHATIAN, MINA	
ART UNIT	**PAPER NUMBER**
1616	

NOTIFICATION DATE	DELIVERY MODE
03/17/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	09/380,310	UKAI ET AL.	
	Examiner	Art Unit	
	Mina Haghighatian	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 December 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21,41,62 and 64-68* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21,41,62 and 64-68* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of the Amendments and Remarks filed on 10/25/07 and supplementary Remarks filed on 12/19/07. Receipt is acknowledged of Evidences A-D.

Claims 22 and 41 have been amended, claims 1-21, 23-40, 42-61 and 63 have been cancelled and new claims 64-68 have been added. Accordingly claims **22, 41, 62 and 64-68** are pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim **68** recites the limitation "the basic medicine of donepezil hydrochloride". This claim depends on claim 41 which does not disclose donepezil hydrochloride. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 41 and 62 are rejected under 35 U.S.C. 102(b) as being anticipated by Tai (5,013,557).

Tai discloses taste masking compositions comprising spray dried microcapsules containing sucralfate and methods for preparing same. The spray dried spheroidal microcapsules comprise in percentages by weight between 1 and 70% of **sucralfate** and between 30 and 99% of a polymer soluble in gastric fluids (col. 5, lines 30-60). The **polymers** soluble in the gastric fluids are polymers which **bind** to **sucralfate** with taste masking properties and **dissolve in gastric fluid**. The suitable polymers include alginic acid, **carrageenan**, xanthan, polyvinylpyrrolidone, etc (col. 6, lines 26-55). It is disclosed that sucralfate is well known in the art as a **basic** aluminum sucrose sulfate complex (see col. 1, lines 45-47 and col. 6, lines 8-12). The formulations may be made into tablets, chewable tablets and spheroidal microcapsules (col. 5, lines 40-50).

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 22 and 65-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tai (5,013,557) in view of Matoba et al (5,464,612) and further in view of Kawakami et al (The Rational for E2020 as a potent acetylcholinesterase inhibitor).

Tai discloses taste masking compositions comprising spray dried microcapsules containing sucralfate and methods for preparing same. The spray dried spheroidal

microcapsules comprise in percentages by weight between 1 and 70% of **sucralfate** and between 30 and 99% of a polymer soluble in gastric fluids (col. 5, lines 30-60). The **polymers** soluble in the gastric fluids are polymers which **bind** to **sucralfate** with taste masking properties and **dissolve in gastric fluid**. The suitable polymers include alginic acid, **carrageenan**, xanthan, polyvinylpyrrolidone, etc (col. 6, lines 26-55). It is disclosed that sucralfate is well known in the art as a **basic** aluminum sucrose sulfate complex (see col. 1, lines 45-47 and col. 6, lines 8-12). The formulations may be made into tablets, chewable tablets and spheroidal microcapsules (col. 5, lines 40-50). Tai lacks specific disclosure on donepezil hydrochloride.

Matoba et al teach a clad powdery or granular preparation of a medicinally active ingredient and a powdery or granular ion exchanger blended to prepare a solid preparation. The active agents are **basic** compounds (see abstract). It is also disclosed that the medicinally active ingredient having an unpleasant taste and/or odor may frequently have a basic group (col. 4, lines 37-39). While Matoba et al does not specifically list donepezil as one of the active agents, it is known in the art that donepezil is a basic compound.

Kawakami et al teach E2020 (also known as donepezil hydrochloride) as a potent acetylcholinesterase inhibitor. E2020 was developed for treatment of Alzheimer's disease, and possibly other dementias.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have modified the formulations of Tai containing a basic medicine with unpleasant taste and an acidic polysaccharide such as carrageenan with other active agents such as donepezil hydrochloride as taught by Kawakami et al in order to prepare more drug formulations with a masked taste for patient convenience and to increase patient compliance. Matoba et al disclose that typically the basic active agents have a bitter taste. In other words, one or ordinary skill in the art having the formulations of Tai and knowing that basic drugs have a bitter taste, would have been motivated to apply the same method to other medications with unpleasant taste in order to provide better tasting medication for patients and increase patient compliance. Additionally, the claims would have been obvious because the technique for improving a particular method was part of the ordinary capabilities of a person of ordinary skill in the art, in view of the teaching of the technique for improvement in other situations.

Claims 64, 67-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tai (5,013,557) in view of Matoba et al (5,464,612) and further in view of Kawakami et al (The Rational for E2020 as a potent acetylcholinesterase inhibitor) as applied to claims 22 and 65-66 above, and further in view of Morikazu et al (JP 4-346937).

The combined references, discussed above, lack specific disclosure on derivatives of carrageenan.

Morikazu teaches a method of simply and economically reducing bitterness of drugs and foods. For that, Morikazu mixes a bitter substance with a gelatininzing agent such as gelatin, *k*-carrageenan, etc and a seasoning agent, preferably a sweetener (see abstract).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made given the general teachings of binding a polymer with a basic active agent of Tai, to have looked in the art for specific agents such as *k*-carrageenan suitable for said formulations as taught by Moikazu with a reasonable expectation of successfully preparing a safe and effective drug formulation without a bitter or unpleasant taste for patients that need such medicaments. In other words, the claims would have been obvious because the substitution of one known element for another would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422

F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims **22, 41, 62 and 64-68** are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3, 6, 12 of U.S. Patent No. **6,576,677** in view of Tai (5,013,557). Claims 22, 41, 62 and 64-68 are not patentably distinct from the reference claims because the claims would have been obvious over the reference claims in view of Tai reference. Specifically, the instant claims are drawn to an oral medicine comprising donepezil hydrochloride and an acidic polysaccharide. Te reference claims are drawn to an oral medicine comprising an active agent such as donepezil hydrochloride and a component such as polyvinylpyrrolidone. Tai teaches a method of making the bitter taste of sucralfate by binding it to a polymer such as carrageenan or polyvinylpyrrolidone. Thus it is taken that Tai is teaching that carrageenan and polyvinylpyrrolidone are equivalent and would lead to the same product. Therefore, the claims would have been obvious because the substitution of one known element for another would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

Response to Arguments

Applicant's arguments filed 10/25/07 and 12/19/07 have been fully considered but they are not persuasive. Applicant's arguments with respect to claims 1, 2, 6-9, 13-16, 20-22, 25, 28-30, 35-37, 40-53, 55-59 and 61-63 have been considered but are moot in view of the new ground(s) of rejection.

Applicant believes that by filing Evidences A-D and the arguments set forth, they have established that "the bitter taste of donepezil hydrochloride was not even known at the time of the priority dates of the present application". This is not found persuasive because the test is not whether the specific bitterness of a drug was known at the time or not but whether it the invention **would have been obvious** to one of ordinary skill in the art at the time of invention. And it has been shown that it would have been obvious. Tai has clearly shown that an active agent with bitter taste can be combined with a polymer such as carrageenan to form solid particles (microcapsules) that are not bitter and dissolve in the gastric fluid (i.e. do not dissolve in the oral cavity). This is the same method used by the applicant. It is considered that the methods of Tai can be implemented in the formulation of any active agent with bitter taste.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mina Haghighatian whose telephone number is 571-272-0615. The examiner can normally be reached on core office hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mina Haghighatian/

Mina Haghighatian
Patent Examiner
February 27, 2008